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DEVELOPMENT OF A NEW PATIENT REPORTED OUTCOME (PRO) MEASURE FOR COMMUNITY-ACQUIRED BACTERIAL PNEUMONIA (CABP)

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OBJECTIVES: We describe the process and progress of the Foundation for the NIH Biomarkers Consortium Project Team, a public-private partnership of government, academia, non-profit, and industry. The goal is development and qualification of a new community-acquired bacterial pneumonia (CABP) patient reported outcome (PRO) instrument incorporating reliable, well-defined, and relevant endpoints for patients in terms of how they feel and function in clinical trials of antibacterial drugs for CABP. **METHODS:** We adhered to the FDA PRO Guidance for instrument development and the 2010 FDA qualification process for drug development tools (DDTs). This guidance describes the process for DDTs intended for use in multiple drug development programs, the goal of the current effort. Once qualified, drug developers can use DDTs for the qualified context in Investigational New Drug (IND) and New Drug Application (NDA)/Biological License Application (BLA) submissions without FDA reconsideration of the DDTs' suitability. **RESULTS:** The initial phase of instrument development included a literature review, a gap analysis, and interviews with six clinical experts. The most commonly reported symptoms identified by the literature review were cough, chest pain, dyspnea, sputum production, and fatigue. These findings were used to inform the development of a study protocol and interview guide to elicit concepts from CABP patients. Following qualitative analysis of the interview transcripts, the team will draft a PRO instrument based on key concepts identified from CABP patients and experts. The draft PRO will be evaluated by an expert panel and refined through cognitive debriefing interviews with patients. **CONCLUSIONS:** A consortium-based approach will be useful and efficient in developing a new draft PRO measure for CABP, which incorporates published literature and data from qualitative interviews. The team is currently using a similar approach for development of a draft PRO for acute bacterial skin and skin structure infections (ABSSSI).

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DETERMINANTS OF QUALITY OF LIFE IN NEWLY DIAGNOSED HIV INFECTED PATIENTS IN KENYA

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OBJECTIVES: Quality of life in HIV infected patients can be determined by a number of factors including severity of disease, social support and coping mechanisms. Common symptoms of HIV can be a key determinant of quality of life. The objective of this study was to examine the influence of symptoms associated with HIV disease on physical and mental of HIV infected patients in Kenya. **METHODS:** A Kiswahili translated SF-12 survey was administered to newly diagnosed HIV infected patients participating in a randomized, controlled trial in Nairobi, Kenya between April and October 2013. Patients were also asked if they were experiencing common symptoms of HIV (i.e. fatigue, loss of appetite, depression or diarrhea) on a scale including no symptoms, mild, moderate or severe symptoms. SF-12 survey responses were scored to derive a physical component score (PCS) and mental component score (MCS). Linear regression was used to determine which symptoms were significantly associated with each score. **RESULTS:** 135 respondents were included in the analysis with 7 observations removed due to missing data. Severe fatigue was associated with 15 point (p<0.01) reduction in PCS while severe lack of appetite was associated with an 8.6 point (p<0.01) reduction in PCS compared patients not experiencing these symptoms. Those experiencing severe depression had 12.2 point (p<0.01) lower MCS and those experiencing severe anxiety had 8.4 point (p<0.01) lower MCS compared to those not experiencing these symptoms. **CONCLUSIONS:** This study is the first to examine which symptoms are associated with lower quality of life outcomes in a cohort of HIV infected patients in Kenya. The drivers of lower physical and mental may be valuable to inform clinical management and program planning efforts in HIV treatment and care.

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SOCIO-DEMOGRAPHIC CHARACTERISTICS RELATED TO QUALITY OF LIFE IN PATIENTS WITH PULMONARY TUBERCULOSIS IN BAGHDAD, IRAQ

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OBJECTIVES: To assess the ability of the socio-demographic characteristics to predict health related quality of life (HRQL) of pulmonary tuberculosis (PTB) patients. **METHODS:** The study was conducted between September 1st 2012 and July 31st 2013, among consecutive PTB patients treated at Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq. Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB); a TB-specific HRQL instrument, along with a structured questionnaire to collect data on socio-demographic characteristics were administered. Standard multiple regression analysis was used to assess the ability of the socio-demographic characteristics (age, marital status, education status, household size, breadwinner, financial status and smoking status) to predict HRQL of PTB patients as measured by FACIT-TB total score. **RESULTS:** Three hundred and five subjects were recruited over a period of 11 months. Participants ranged in age from 18 to 91 years, 64.6% of them were male and 28.2% were illiterate. Furthermore, 50.8% of the patients in the sample were the major breadwinners for their families. The variables in the model explained 22.9% of the variance in the FACIT-TB total score, $F(7,286) = 12.14$, $P < 0.001$. Among the seven variables, education status, being the breadwinner, financial status, and smoking showed a significant bivariate relationship with the FACIT-TB total score. Correlations between these seven variables precluded the condition of

high co-variability, when $r \geq 0.7$, for regression analysis. The results of simple linear regression indicated that education status accounted for the greatest variance of the FACIT-TB total score, when the variance explained by all other variables in the model is controlled for (Beta = 0.325, $P < 0.001$), followed by financial status and smoking status. **CONCLUSIONS:** Our results confirmed that poor educational and financial statuses as well as being smokers are independent determinant of poor HRQL of PTB patients in Iraq.

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HEALTH RELATED QUALITY OF LIFE OF PEOPLE LIVING WITH HIV/AIDS ATTENDING THE ANTI-RETROVIRAL CLINIC IN THE UNIVERSITY OF BENIN TEACHING HOSPITAL, BENIN CITY

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OBJECTIVES: 1) To assess the overall Quality Of Life (QOL) of people living with HIV/AIDS (PLWHA); 2) To compare the QOL in the six domains of health; and 3) To determine any association between age, gender, educational level and QOL. **METHODS:** The study design is a descriptive cross sectional survey and the study population included all PLWHA who have enrolled into the Anti-Retroviral Therapy pharmacy of the University of Benin Teaching Hospital and were currently receiving their Highly Active Antiretroviral Therapy (HAART) for a period of at least six months. A trained interviewer administered a questionnaire that collects data on socio-demographics, clinicals and the items of World Health Organization Quality Of Life (WHOQOL) HIV-brief from each participant. Means, standard deviations, and statistical tests for differences were performed. **RESULTS:** A total of 360 respondents were surveyed. The mean age of the group was 38.58 years. 262 (72.8%) of respondents were females. The overall QOL of respondents was good with a mean score of (3.8 ± 0.81). The QOL mean score were highest for the spirituality/religion/personal belief domain (16.03 ± 0.97) and lowest for the social relationships domain (11.38 ± 1.01). The age of the respondents showed statistically significant differences ($P < 0.05$) in all domains of QOL except in the level of independence domain. Respondents in all the age groups had poor QOL in the social relationships domain. Females had statistically significant higher QOL mean scores in the physical, psychological and spirituality/religion/personal beliefs domains ($P < 0.05$) compared to males. The educational level of respondents showed statistically significant differences ($P < 0.05$) in physical, psychological, social relationships and spirituality/religion/personal beliefs domains. Respondents with Tertiary education had higher QOL mean scores in the six domains of health. **CONCLUSIONS:** The study revealed good overall QOL among respondents. The mean QOL scores were highest in the spirituality/religion/personal beliefs domain and lowest in the social relationships.

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THE ASSESSMENT OF PATIENTS' HEALTH RELATED QUALITY OF LIFE DURING THE COURSE OF TUBERCULOSIS TREATMENT IN BAGHDAD, IRAQ

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OBJECTIVES: Quality of life (QoL) has become an accepted outcome measure in clinical research and advances have been made in assessing the impact of many diseases on QoL. The current study aimed to assess health related quality of life (HRQL) of subjects treated for active pulmonary tuberculosis (PTB) during the course of tuberculosis (TB) treatment. **METHODS:** Consecutive PTB patients treated at Thoracic and Respiratory Disease Specialist Centre in Baghdad, Iraq were administered a validated TB-specific instrument. The Functional Assessment of Chronic Illness Therapy-Tuberculosis (FACIT-TB) total score and its subscales score at onset of treatment, after the intensive phase, and after completion of TB treatment were compared. **RESULTS:** A total of 136 PTB patients were included in the analysis. After 2 months, physical well-being (PWB), functional well-being (FWB), and FACIT-TB total scores were significantly increased ($P < 0.01$). However, there were no statistical significant differences in social and economic well-being (SEWB), emotional well-being/living with TB (EWB/TB), and spiritual well-being (SpWB) subscales score. Furthermore, a significant improvement was observed in overall HRQL as indicated by FACIT-TB total score and all subscales except SEWB and SpWB at completion of TB treatment. **CONCLUSIONS:** The gradual increase in PWB, FWB and EWB/TB subscale scores over the course of TB treatment indicate the positive effect of medical therapy on patients' QoL. However, interventions to offset social distress and dysfunction are important. Therefore individual's perception toward this dimension of QoL should be addressed in future research.

INFECTION – Health Care Use & Policy Studies

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A MODEL OF CLOSTRIDIUM DIFFICILE INFECTION: DYNAMIC TRANSMISSION BETWEEN HOSPITALS, LONG-TERM CARE FACILITIES AND COMMUNITIES

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OBJECTIVES: The transmission of *C difficile* infection (CDI) has recently changed, resulting in a five-fold increase in the incidence in the general population and an eight-fold increase among the elderly. We developed a simulation model to examine the dynamic relationship between three major subpopulations of CDI transmission: hospitals, long-term care facilities (LTCF), and communities, to evaluate treatment effectiveness and costs. **METHODS:** A stochastic agent-tracking meta-population network model of CDI transmission has been developed. A framework for contagion dynamics between the three subpopulations (hospitals, LTCF and communities) was employed. We identified eight health states: susceptible, gastrointestinal exposure, colonized, diseased, clinically resolved colonized, relapsed, cleared, and deceased. Key parameters include: age-specific incidence rates, disease severity, hospital LOS,